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10/800,339	03/12/2004	James W. Voegelé	END5241USNP	9931

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EXAMINER
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NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

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01/14/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/800,339	<b>Applicant(s)</b> VOEGELE, JAMES W.	
	<b>Examiner</b> HELEN NGUYEN	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,5-7 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5-7 and 21-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/14/2008</u>  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. This Office Action is responsive to the RCE filed 10/14/2008. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/14/2008 has been entered.
2. Claim 1 is amended and Claim 4 is cancelled. **Claims 1, 5-7, and 21-34** remain pending and under prosecution.

### ***Information Disclosure Statement***

3. The information disclosure statement (IDS) submitted on 10/14/2008 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Objections***

4. **Claims 1 and 5-7** are objected to because of the following informalities: regarding Claim 1 it is believed paragraph two should recite "at least two electrodes" not "at two least electrodes." Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1, 5, 21-23, 30-31, and 33** are rejected under 35 U.S.C. 102(e) as being anticipated by Shadduck (US Pat No. 6740082).

7. In regard to **Claims 1 and 5**, Shadduck discloses a device comprising:

a hollow sleeve 305 adapted to receive a tissue piercing element therein, the sleeve comprising an open proximal end, a distal end, a sidewall extending between the proximal end and the distal end, best seen in Figure 13A, and a tissue receiving opening (near element 45a) disposed intermediate the proximal end and the distal end, wherein the tissue receiving opening is formed laterally in the sidewall, best seen in Figure 13A;

at least two electrodes 45a, 45b disposed on the sleeve, best seen in Figure 13A wherein the at least two electrodes are capable of and thus adapted for providing coagulation, and such that at least a portion of each electrode is positioned proximally of the a distal most portion of the tissue receiving opening and wherein at least a portion of each electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 13A.

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8. In regard to **Claims 21-23, 30-31, and 33**, Shadduck discloses a device comprising:

a hollow sleeve 305 comprising a proximal end, a distal end, and an unitary sidewall extending from the distal end to the proximal end, best seen in Figure 13A, and a lateral opening (near element 45a) formed through a portion the unitary sidewall, wherein the lateral opening is capable of and thus configured to receive tissue, also see Figure 6B, wherein the sleeve is configured to axially receive a portion of a biopsy probe instrument such as instrument 310, best seen in Figure 13A;

at least one electrode 45a, 45b disposed on an outer surface of the sleeve, wherein at least a portion of the electrode is disposed proximally of a distal most portion of the lateral opening, best seen in Figure 6B and 13A.

9. **Claims 1, 5, 21-23, 30-31, and 33** are rejected under 35 U.S.C. 102(b) as being anticipated by Truckai et al (US Pat No. 6485436).

10. In regard to **Claims 1 and 5**, Truckai et al disclose a biopsy device comprising:

a hollow sleeve 110A adapted to receive a tissue piercing element therein, the sleeve comprising an open proximal end, a distal end, a sidewall extending between the proximal end and the distal end, best seen in Figure 7, and a tissue receiving opening disposed intermediate the proximal end and the distal end, wherein the tissue receiving opening is formed laterally in the sidewall, best seen in Figure 7;

at least two electrodes 196 (Col.6: 60-61 – paired bi-polar electrodes) disposed on the sleeve, best seen in Figure 7, wherein the at least two electrodes are capable of and thus adapted

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for providing coagulation, and such that at least a portion of each electrode is positioned proximally of the a distal most portion of the tissue receiving opening and wherein at least a portion of each electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 7.

11. In regard to **Claims 21-23, 30-31, and 33**, Truckai et al disclose a biopsy device comprising:

a hollow sleeve 110A comprising a proximal end, a distal end, and an unitary sidewall extending from the distal end to the proximal end, best seen in Figure 7, and a lateral opening formed through a portion the unitary sidewall, wherein the lateral opening is configured to receive tissue, wherein the sleeve is configured to axially receive a portion of a biopsy probe 110B, best seen in Figure 7;

at least one electrode 196 disposed on an outer surface of the sleeve, wherein at least a portion of the electrode is disposed proximally of a distal most portion of the lateral opening, best seen in Figure 7.

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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13. **Claims 1, 5-6, and 34** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al (US Publication No. 2002/0120211) in view of Truckai et al (US Pat No. 6485436) or Shadduck (US Pat No. 6740082).

14. In regards to **Claim 1**, Wardle et al discloses a biopsy device comprising:

a hollow sleeve (14) adapted to receive a tissue piercing element (72) therein, the sleeve comprising an open proximal end, a distal end, a sidewall extending between the proximal end and the distal end, best seen in Figure 2B, and a tissue receiving opening (22, 26) disposed intermediate the proximal end and the distal end, wherein the tissue receiving opening is formed laterally in the sidewall, best seen in Figures 1 and 2B;

at least two electrodes (20) disposed on the sleeve, best seen in Figure 2B (left and right) wherein the at least two electrodes are capable of and thus adapted for providing coagulation (¶0030).

15. However, Wardle et al do not disclose the electrodes disposed such that at least a portion of each electrode is positioned proximally of the a distal most portion of the tissue receiving opening and wherein at least a portion of each electrode is positioned distally of a proximal most portion of the tissue receiving opening. Truckai et al disclose an analogous biopsy device comprising an electrode 196 disposed on an outer sleeve 110A such that at least a portion of the electrode is positioned proximally of the a distal most portion of a tissue receiving opening and wherein at least a portion of the electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 7. Shadduck teaches an analogous sleeve comprising at least two electrodes 45a, 45b disposed on the sleeve 305 such that at least a portion

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of each electrode is positioned proximally of the a distal most portion of a tissue receiving opening and wherein at least a portion of each electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 13A.

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the configuration of the electrodes of Wardle et al such that the at least two electrodes are disposed on the sleeve in the manner above as taught by Truckai et al or Shadduck as an equally as effective configuration to achieve the predictable result of proper biopsy of tissue.

17. In regards to **Claim 5**, Wardle et al and Truckai et al or Shadduck disclose first and second electrodes (20) associated with the edges of the tissue receiving opening (22).

18. In regards to **Claim 6**, Wardle et al disclose a connector for releasably attaching the sleeve to a biopsy device, best seen in Figure 4.

19. In regards to **Claim 34**, Wardle et al disclose a biopsy for obtaining a tissue sample at a sample site within a patient, the biopsy device comprising:

a hollow tissue piercing member (14) having a tissue piercing distal end (¶0030) and a tissue receiving port (22, 26) spaced proximally from the tissue piercing distal end, the hollow tissue piercing member insertable in a tissue mass within a patient, best seen in Figure 1 and 2B;

a hollow cutter (72, 44) translatable within the hollow tissue piercing member for severing tissue received in the tissue receiving port at a sample site within the tissue mass, best seen in Figure 4;



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at least one electrode (20) disposed outwardly of the hollow tissue piercing member, the at least one electrode capable of and thus adapted to provide coagulation at the sample site after a tissue sample is severed by the cutter.

20. However, Wardle et al do not disclose the electrode disposed such that at least a portion of the electrode is positioned proximally of the a distal most portion of the tissue receiving opening and wherein at least a portion of the electrode is positioned distally of a proximal most portion of the tissue receiving opening. Truckai et al disclose an analogous biopsy device comprising an electrode 196 disposed on an outer sleeve 110A such that at least a portion of the electrode is positioned proximally of the a distal most portion of a tissue receiving opening and wherein at least a portion of the electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 7. Shadduck teaches an analogous sleeve comprising at least two electrodes 45a, 45b disposed on the sleeve 305 such that at least a portion of each electrode is positioned proximally of the a distal most portion of a tissue receiving opening and wherein at least a portion of each electrode is positioned distally of a proximal most portion of the tissue receiving opening, best seen in Figure 13A.

21. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the configuration of the electrodes of Wardle et al such that the at least one electrode is disposed on the sleeve in the manner above as taught by Truckai et al or Shadduck as an equally as effective configuration to achieve the predictable result of proper biopsy of tissue.

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***Claim Rejections - 35 USC § 103***

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. **Claims 21-25, and 27-33** are rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al in view of Shadduck (US Pat No. 6740082).

24. In regards to **Claim 21**, Wardle et al disclose a biopsy device comprising:

a hollow sleeve (14) comprising a proximal end, a distal end, and an unitary sidewall extending from the distal end to the proximal end, best seen in Figure 2B, and a lateral opening (22, 26) formed through a portion the unitary sidewall, wherein the lateral opening is configured to receive tissue, wherein the sleeve is configured to axially receive a portion of a biopsy probe instrument (44);

at least one electrode (20) disposed on an outer surface of the sleeve, best seen in Figure 2B.

25. However, Wardle et al do not disclose said at least one electrode disposed proximally of a distal most portion of the lateral opening. Shadduck discloses an analogous sleeve comprising electrodes (45a-b) disposed proximally of a distal most portion of a lateral opening (76), as an effective configuration for the desired tissue contact, best seen in Figure 6B. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

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substitute the positioning of the electrode of Wardle et al such that said electrode is disposed proximally of a distal most portion of the lateral opening, as taught by Shadduck, to produce an effective electrode configuration that enhances tissue contact to achieve the predictable result of proper tissue biopsy.

26. In regards to **Claim 22**, Wardle et al disclose the lateral opening (22) is located proximal of the distal end of the sleeve, wherein a portion of the sleeve separates the lateral opening from the distal end of the sleeve, best seen in Figure 2B.

27. In regards to **Claim 23**, Wardle et al disclose a portion of the sidewall extends unitarily from the proximal end of the sleeve to the distal end of the sleeve, best seen in Figure 2B.

28. In regards to **Claim 24**, Wardle et al disclose a connector operable to selectively couple the sleeve with the biopsy probe instrument, best seen in Figure 4.

29. In regards to **Claim 25**, Wardle et al disclose the sleeve (14) has an open distal end (22, 26), which is an opening at the distal end, wherein the sleeve is configured to axially receive a biopsy probe (44) having a distal tip (72) for penetrating tissue, and wherein the sleeve is configured such that the distal tip of a biopsy probe extends distally from the open distal end of the sleeve when the sleeve is disposed axially over the biopsy probe, best seen in Figures 2-3.

30. In regards to **Claim 27**, Wardle et al disclose the biopsy probe instrument is configured to communicate electrical signals to the electrodes (20) when the sleeve (14) is coupled with the biopsy probe instrument (¶0034-0035).

31. In regards to **Claim 28**, Wardle et al disclose the electrodes (20) are configured and

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capable to receive communication of electrical signals for a power source independent of the biopsy probe instrument.

32. In regards to **Claim 29**, Wardle et al in combination with Shadduck disclose first and second electrodes positioned along opposites of the lateral opening (22, 26), wherein such variable positioning is obvious to one of ordinary skill in the art, such as that shown in Shadduck Figure 6A.

33. In regards to **Claim 30**, Wardle et al in combination with Shadduck disclose the one or more electrodes comprises an annular electrode positioned at the distal end of the sleeve (14).

34. In regards to **Claim 31**, Wardle et al in combination with Shadduck disclose the one or more electrodes comprises a pair of electrodes separated by an electrode gap, best seen in Figure 6B (Shadduck).

35. In regards to **Claim 32**, Wardle et al disclose the distal end of the sleeve (14) is open (22, 26), wherein there is an opening at the distal end of the sleeve, best seen in Figure 2B.

36. In regards to **Claim 33**, Wardle et al in combination with Shadduck disclose two electrodes, each electrode extending lengthwise in a direction parallel to the longitudinal axis of the sleeve, and at least a portion of each electrode disposed proximally of a distal most portion of the lateral opening, best seen in Figure 6B (Shadduck).

37. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al and Truckai et al or Shadduck in view of Burbank et al (US Pat No. 6540695) and Russell et al (US Pat No. 6500144).

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38. Wardle et al and Truckai et al or Shadduck disclose at least two electrodes (20) disposed on an outer surface of the sleeve (14) but are silent as to the dimensions of the electrodes (20). Burbank et al teach electrodes (18), best seen in Figure 1, with a width dimension of between about 3 mm and about 8 mm (Col.11: 58-67). Russell et al teach electrodes (20), best seen in Figure 1, with a length dimension of between about 20 mm and about 40 mm (Col.7: 4-15) as effective sizes for the desired tissue application within the body. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the at least two electrodes of Wardle et al and Truckai et al or Shadduck with a width of about 3mm – 8 mm and a length of about 20 mm – 40 mm, as taught by Burbank et al and Russell et al respectively, to dimension the electrodes at an appropriate size for the desired tissue application.

39. **Claim 26 is** rejected under 35 U.S.C. 103(a) as being unpatentable over Wardle et al in view of Shadduck, further in view of Burbank et al (US Pat No. 5526822).

40. Wardle et al in combination with Shadduck disclose the sleeve (14) with a lateral opening (22, 26) for tissue communication and a biopsy probe instrument (44) but do not disclose said biopsy probe instrument with a tissue receiving window. Burbank et al disclose an analogous biopsy probe instrument (468) with a tissue receiving window (476) disposed within an analogous sleeve (444) also with a lateral opening (446), best seen in Figure 14A, wherein when the sleeve is coupled with the biopsy probe instrument, the sleeve is configured such that the lateral opening permits communication of tissue through the lateral opening of the sleeve and through the tissue receiving window of the biopsy probe instrument (Col.18: 53-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

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to modify the biopsy probe instrument of Wardle et al as modified by Shadduck to include a tissue receiving window, as taught by Burbank et al, such that when said biopsy probe instrument is coupled to the sleeve the lateral opening of the sleeve enables communication of tissue through the lateral opening and through the tissue receiving port to ensure the prolapse and subsequent effective capture of the tissue.

### ***Response to Arguments***

41. Applicant's arguments filed 10/14/2008 have been fully considered but they are not persuasive. Applicant contends that the modification of Wardle et al with Truckai et al or Shadduck would be counter to the teachings of Wardle et al because Wardle et al teach "distal tip cutter 20" used for "opening up a path through which distal portion 18 of shaft 14 may be inserted." However, it is noted that Wardle et al merely disclose "distal" tip cutter 20, which does not necessarily require said cutter to be disposed at the distal~~most~~ position. In fact, Wardle et al explicitly teach that "distal tip cutter 20 is preferably spaced away from the shaft distal tip 16" see ¶0030 line 11-12. Furthermore, it is noted that the modification of Wardle et al to place the electrodes in the manner elaborated above would not prevent use of said electrodes to "open up a path for the distal portion of shaft 14" considering that the electrodes are still disposed in relatively the same distal position of the sleeve and would thus still function as such.

42. Therefore, it is maintained that the combination of Wardle et al with Truckai et al or Shadduck to modify the positioning of the electrodes is not only proper but also highly motivated by the simple substitution of one known configuration of electrodes for another known

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configuration which would have been obvious to one of ordinary skill in the art by yielding predictable results to one skilled in the art at the time of the invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./

Examiner, Art Unit 3736

/Max Hindenburg/

Supervisory Patent Examiner, Art Unit 3736

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